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May 8, 2024

REDACTED - PUBLIC VERSION

The Honorable Jennifer L. Hall
United States District Court
for the District of Delaware
844 North King Street
Wilmington, DE 19801-3555

VIA ELECTRONIC FILING

Re: *Nippon Shinyaku Co., Ltd. v. Sarepta Therapeutics, Inc.*;
C.A. No. 21-1015 (JLH)

Dear Judge Hall:

We write on behalf of Sarepta Therapeutics, Inc. (“Sarepta”) and the University of Western Australia (“UWA”) in response to NS’s Letter Brief (D.I. 568). For the reasons below, the Court should deny NS’s requests to limit Sarepta’s damages and impose sanctions.

I. SAREPTA HAS HAD CONTINUOUS EXCLUSIVE RIGHTS

Sarepta has possessed exclusionary rights in the ’851 Patent, including the exclusive U.S. rights to manufacture and commercialize VYONDYS 53[®] and sue for infringement, since before this case was filed and for the entire damages period.

A party that has “the right to exclude others from making, using, and selling an invention described in the claims of a patent is constitutionally injured by another entity that makes, uses, or sells the invention.” *Intell. Prop. Dev., Inc. v. TCI Cablevision of Calif., Inc.*, 248 F.3d 1333, 1346 (Fed. Cir. 2001). The Federal Circuit has explained that “constitutional standing is satisfied when a party holds *at least one exclusionary right*.” *Univ. of S. Fla. Rsch. Found., Inc. v. Fujifilm Med. Sys. USA, Inc.*, 19 F.4th 1315, 1324 (Fed. Cir. 2021) (emphasis added). Exclusionary rights involve the ability to exclude others from practicing an invention or to “forbid activities that would normally be prohibited under the patent statutes.” *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1342 (Fed. Cir. 2007).

UWA granted Sarepta an exclusive license to the ’851 Patent in 2008, which was restated in 2013. NS Exs. C, E.

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[REDACTED]; *Calgon Corp. v. Nalco Chem. Co.*, 726 F. Supp. 983, 986 (D. Del. 1989) (explaining that the “most important[]” substantial right in any patent is “the right to sue infringers”). [REDACTED]

[REDACTED] This agreement was memorialized in three documents: [REDACTED]

[REDACTED] All three agreements (1) were drafted together [REDACTED], (2) were made effective as of [REDACTED], and (3) functioned together as a unified understanding (irrespective of when they were signed). Ex. 4, Walsh Decl. at ¶¶ 3-5. Thus, [REDACTED]

[REDACTED] This is confirmed by the express language of [REDACTED]

[REDACTED] These agreements have remained in force through present day and confirm that Sarepta has continuously maintained exclusionary rights at all relevant times.

NS’s sole complaint appears to be that, despite having the same effective date, because the [REDACTED] was signed before [REDACTED], Sarepta’s exclusive rights under [REDACTED] evaporated before [REDACTED] came into effect, creating a gap in Sarepta’s exclusivity. But that fails for multiple reasons. *First*, [REDACTED] expressly states that at the time of its execution, [REDACTED], making clear the parties’ intent and understanding that [REDACTED]. NS argues that this language is meaningless simply because it is found in the recitals. To the contrary, its presence in the recitals undisputedly proves that the parties understood those rights to already have been effective. *Second*, the stated reason for terminating the [REDACTED] was that [REDACTED]

[REDACTED] So, if [REDACTED] as NS suggests, the [REDACTED] would still have been necessary and [REDACTED]. *Third*, the parties began performing under the agreements [REDACTED], with Sarepta continuing as the exclusive manufacturer and seller of patented products in the U.S. and booking the [REDACTED] royalty specified in the new agreements. Walsh Decl. at ¶¶ 5-21. Performance is strong evidence of the existence of an agreement. *In re Abbale*, 475 B.R. 334, 339 (Bankr. E.D.N.Y. 2012) (citing *Viacom Int’l Inc. v. Tandem Prods., Inc.*, 368 F. Supp. 1264 (S.D.N.Y. 1974)). *Fourth*, as a matter of law, that several of the documents were *signed* [REDACTED], does not mean there was no agreement as of that date. Agreement had been reached on the substance of the agreements, and the parties were performing [REDACTED] as if they were in place, rendering them enforceable. *See Flores v. Lower E. Side Serv. Ctr., Inc.*, 4 N.Y.3d 363, 368 (2005) (“[A] contract may be valid even if it is not signed by the party to be charged, provided its subject

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matter does not implicate a statute ... that imposes such a requirement.”); *id.* at 369 (“[A]n unsigned contract may be enforceable, provided there is objective evidence establishing that the parties intended to be bound.”). **Finally**, NS’s argument is internally inconsistent. All three documents form a single agreement. Either they were all in force together or not at all.¹ NS improperly asks this Court to assume that one of the three documents ([REDACTED]) was enforceable [REDACTED] despite not being signed [REDACTED], but that the other two—also having [REDACTED]—were not effective until [REDACTED]. NS cannot have it both ways. Under any consistent interpretation of the agreements, Sarepta never lost its exclusive rights.²

II. NO SANCTIONS ARE WARRANTED

NS first raised this issue eight days ago, on April 30, 2024, based on an agreement that Sarepta produced on November 4, 2022 and that NS used at a deposition on July 25, 2023. Sarepta immediately investigated the issue, producing additional agreements as soon as they were identified. While Sarepta certainly wishes these documents had been located and produced earlier, it conducted a reasonable and good faith review (resulting in a production of more than 230,000 pages), and the documents were just missed, as sometimes happens in complex litigation.³

¹ If [REDACTED] was not in force, Sarepta was still the exclusive licensee by virtue of the [REDACTED] until such time as the agreement did come into force. *See* NS Ex. H at ¶ 7.2 ([REDACTED]); *see also* NS Ex. J ([REDACTED]) at ¶ 2 (referencing the same provision).

² Even in the absence of an express agreement between [REDACTED], an implied exclusive license would have existed [REDACTED]. *Aspex Eyewear, Inc. v. Altair Eyewear, Inc.*, 288 Fed. Appx. 697, 705 (Fed. Cir. 2008). An implied exclusive license confers standing to sue for both equitable and monetary relief. *Alarm.com, Inc. v. SecureNet Techs. LLC*, 345 F. Supp. 3d 544, 552 (D. Del. 2018). Courts have often found parties acting as the exclusive seller of patented products, as Sarepta was here, to possess such an implied exclusive license. *Weinar v. Rollform Inc.*, 744 F.2d 797, 807 (Fed. Cir. 1984) (affirming the existence of an exclusive license when the party acted as the exclusive seller in the U.S.); *Luis Medina & Evatech, Inc. v. Wright*, No. 8:10-CV-2134-MSS-AEP, 2014 WL 12618175, at *2 (M.D. Fla. Dec. 4, 2014) (finding an implied exclusive license existed when, as here, there was undisputed evidence that the party was the only manufacturer and seller of the patented invention). This flexibility is particularly true of relationships between [REDACTED].

³By way of explanation and not excuse, [REDACTED]
[REDACTED] Other of the produced documents were not

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In any event, immediately upon NS's request last Tuesday, Sarepta investigated the issue on a round-the-clock basis and was able to answer NS's inquiry, and locate and produce related documents, within three days. NS Ex. L at 10-11. NS requested more detail on May 5, and 16 hours later, Sarepta again provided responsive information and documents.⁴ *Id.* at 4-6. NS now inexplicably divides Sarepta's production into two separate buckets based merely on whether they were provided on May 3 or May 6 (just one business day later), and seeks different sanctions for each bucket. But sanctions of any type are improper under Fed. R. Civ. P. 37(c)(1) if the productions are "substantially justified or . . . harmless." The reality is that while NS seemingly perceived a problem by reading some of the agreements on Friday, it was clear by Monday that there was no issue with standing. *See* D.I. 570 at 85:20-22 (NS counsel stating "when somebody says 'standing,' that usually implicates a bigger deal"). Evaluating the governing *Pennypack* factors establishes that no sanctions are warranted.

Factor 1 (prejudice or surprise): For the reasons above, the produced documents do not diminish Sarepta's entitlement to damages, and NS has suffered no actual prejudice. Even NS concedes that [REDACTED] (D.I. 568 at 4) and therefore there is no prejudice to its own offensive case. Moreover, NS can hardly claim surprise in light of its (1) admission that it was aware of (but did not follow up on) an entity issue during fact discovery (NS Ex. L at 12) and (2) agreement to stipulate to related facts in the pretrial order. *IPA Techs. Inc. v. Microsoft Corp.*, No. CV 18-1-RGA, 2024 WL 1797394, at *9 (D. Del. Apr. 25, 2024) ("Plaintiff does not face prejudice as it failed to raise this issue at an earlier time when corrective action could have been taken.").

Factors 2 (ability to cure) and 3 (orderly and efficient trial): Given that the newly-produced documents only reinforce Sarepta's entitlement to damages, there is no prejudice to cure and trial need not be disrupted. Even if the Court were to agree with NS that Sarepta "cannot seek or recover lost profits for [REDACTED]" (D.I. 568 at 1), such a ruling would be easily implemented and, per NS's cited case law, would result in nothing more than "updated numbers . . . plugged into a previously disclosed and unchanged formula." *Siemens Mobility Inc. v. Westinghouse Air Brake Techs. Corp.*, 2019 WL 9698520, at *2 n.1 (D. Del. Jan. 2, 2019).⁵

readily recognizable as relevant. As one example, [REDACTED]
[REDACTED]

⁴ The May 6 production is both harmless and "substantially justified" because those documents were specifically demanded by NS to provide context to the May 3 documents. That NS may not like what they say is no reason to exclude them.

⁵ NS is unwilling to proceed with trial next week if the Court amends the construction of "base sequence" as proposed. D.I. 569 at 3. But if the Court is inclined to proceed, the present dispute is no reason to hold up any part of the trial. The verdict form could ask the jury to address two damages periods, the parties could agree that the dispute applies to a certain percentage of Sarepta's damages award, or the Court could resolve the question. Courts retain broad discretion to "determine the content and structure of the verdict form" to give force to jury verdicts. *See, e.g.,*

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Factor 4 (bad faith/willfulness): NS does not accuse Sarepta of bad faith, and rightfully so. While Sarepta would certainly have preferred for these documents to have been captured in earlier collections, Sarepta produced more than 230,000 pages from its and its former employees' files. It cannot be "gross negligence" or a "willful failure" for [REDACTED]. Sarepta engaged in document production diligently and in good faith—just as it did in short order following NS's April 30 request.

Factor 5 (importance): Courts have observed that the fifth *Pennypack* factor "is often the most significant factor." *See, e.g., ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 298 (3d Cir. 2012) (citation omitted). Here, NS essentially concedes the importance of these documents. For the May 3 documents, NS does not seek exclusion, and indeed devotes much of its letter brief to their importance. And the May 6 documents were produced *at NS's request* to provide context for the May 3 documents, which are now part of the case. NS should not be permitted to cherry pick which portions of interrelated evidence to keep or discard, based on an arbitrary difference of one business day on when they were produced. Exclusion of "critical evidence"—which NS concedes these documents are—"is an extreme sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994) (internal quotation omitted). At bottom, the entire coherent set of documents evidence Sarepta's entitlement to lost profits for NS's adjudicated infringement of a presumptively valid patent. The Supreme Court has highlighted this as the primary inquiry for the factfinder: "had the Infringer not infringed, what would Patent Holder-Licensee have made?" *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 507 (1964) (citation omitted). For the factfinder here—the jury—these documents aid that effort.

Accordingly, Sarepta's May 3 and May 6 productions were harmless and/or substantially justified. No sanctions are warranted under Rule 37(c)(1) with regard to the May 3 documents, and exclusion of the May 6 documents is not justified. This case is ready for trial.

We will be prepared to discuss the above positions at tomorrow's continued pretrial conference.

Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

cc: All Counsel of Record (via CM/ECF and e-mail)

Finjan, Inc. v. Symantec Corp., No. 10-CV-593 (GMS), 2013 WL 5302560, at *47 (D. Del. Sept. 19, 2013), *aff'd*, 577 F. App'x 999 (Fed. Cir. 2014).